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Dec. 22, 2008
Date

Joanne Bourguignon

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	James I. Mullins et al.
Application No.	:	10/780,507
Filed	:	February 17, 2004
For	:	ANCESTRAL AND COT VIRAL SEQUENCES, PROTEINS AND IMMUNOGENIC COMPOSITIONS
Examiner	:	PENG, Bo
Art Unit	:	1648
Docket No.	:	2478-3150-4679PT
Date	:	December 22, 2008

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
ATTENTION: Board of Patent Appeals and Interferences

APPEAL BRIEF TRANSMITTAL AND
EXTENSION OF TIME

Sir:

Transmitted herewith, is the Appeal Brief in this application, with respect to the Notice of Appeal filed on June 22, 2008. The Commissioner is hereby authorized to charge the fee of $270 for filing this Appeal Brief to Deposit Account No. 50-2976.

Please extend the period of response for Application No. for four months, from September 22, 2008 to December 22, 2008. The Commissioner is hereby also authorized to charge the four months extension fee of $865 to Deposit Account No. 50-2976.

The Commissioner is hereby authorized to charge any fees in conjunction with this communication or to credit any overpayment to Deposit Account No. 50-2976. At anytime during the pendency of this application, please charge any fees required or credit any overpayment to Deposit Account No. 50-2976 pursuant to 37 CFR 1.25. Additionally, please

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charge any fees to Deposit Account No. 50-2976 under 37 CFR 1.16 through 1.21 inclusive, and any other sections in Title 37 of the Code of Federal Regulations that may regulate fees. This notice is being submitted in duplicate.

Respectfully submitted,
James I. Mullins et al.
OLYMPIC PATENT WORKS PLLC

Robert W. Bergstrom
Registration No. 39,906

Enclosures:
Postcard
Appeal Brief
Copy of this Transmittal/Petition

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In re patent application of:

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APPEAL BRIEF

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Sir:

This appeal is from the decision of the Examiner, in an Office Action mailed January 22, 2008, finally rejecting claims 15, 19-22, 25-30, 45, 46, 48 and 63.

REAL PARTY IN INTEREST

The real party in interest is the University of Washington, 4311 11th Ave., NE, Suite 500, Seattle, WA 98105-4608.

RELATED APPEALS AND INTERFERENCES

Applicant's representative has not identified, and does not know of, any other appeals of interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 15, 19-22, 25-30, 45, 46, 48 and 63 are pending in the application. Claims 15, 19-22, 25-30, 45, 46, 48 and 63 were finally rejected in the Office Action dated January 22, 2008. Applicants' appeal the final rejection of claims 15, 19-22, 25-30, 45, 46, 48 and 63 which are copied in the attached CLAIMS APPENDIX.

STATUS OF AMENDMENTS

No Amendment After Final is enclosed with this brief. The last Amendment was filed August 7, 2007.

SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 15

Claim 15 is directed to an isolated expression construct comprising the following operably linked elements: a transcriptional promoter; a nucleic acid sequence that encodes the polypeptide encoded by SEQ ID NO:25 (Sequence Listing, pages 21-22; Figure 9) ; and a transcriptional terminator (paragraph [0020] on page 5).

Independent Claim 45

Claim is directed to an isolated COT viral gene sequence (paragraph [0014] on page 4), wherein the sequence is at least 70% identical to SEQ ID NO:25 (Sequence Listing, pages 21-22; Figure 9).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. The rejection of claims 15, 19-22, 25-30, 45, 46, 48, and 63 under 35 U.S.C. §112, first paragraph, as lacking enablement.

ARGUMENT

Claims 15, 19-22, 25-30, 45, 46, 48, and 63 are pending in the current application. In an office action dated January 22, 2008 ("Office Action"), the Examiner objected to claims 45, 46, and 48, rejected claim 48 under 35 U.S.C. §112, second paragraph,

rejected claims 45, 46, and 48 under 35 U.S.C. §112, first paragraph, rejected claims 15, 19-22, 25-30, 45, 46, 48, and 63 under 35 U.S.C. §112 with respect to the scope of enablement, rejected claims 45 and 46 under 35 U.S.C. §102 as being anticipated by Shiver, WO 98/34640 and/or Gray, U.S. Patent No. 6,958,226. Applicants respectfully traverse the 35 U.S.C. §112 rejection of claims 15, 19-22, 25-30, 45, 46, 48, and 63.

ISSUE 1

1. The rejection of claims 15, 19-22, 25-30, 45, 46, 48, and 63 under 35 U.S.C. §112, first paragraph, as lacking enablement.

In section 16 on page 5 of the Office Action, the Examiner states: "Applicant's argument is not convincing because the specification has not shown how to use the alleged COT sequence for any diagnostic uses." Applicants' current representative, in cursorily reading the application, immediately found, in paragraphs [0248] and [0249] on page 70 of the current application, a section describing using COT viral sequences for diagnosing viral infection. Clearly, the Examiner's statement clearly is incorrect.

In section 17 of the Office Action, the Examiner states that "it is unpredictable in the art what the outcomes/advantages of the COT sequences are over wild type sequences for their use as vaccine." The Examiner fails to cite any statute or rule that would support a 35 U.S.C. §112 rejection based on a failure to state advantages of the currently claimed invention over use of wild-type sequences. Applicants' current representative is unaware of a rule or statute that would support this rejection. The fact that no rule or statute was cited is a clear error.

In section 18 of the Office Action, the Examiner states: "In the instant case, the instant claimed invention is unpredictable since the state of art is silent regarding how to use the artificial COT sequences generated by mathematic manipulation as vaccine regiments or diagnostic probes." This statement makes absolutely no sense. The prior art is silent regarding this issue because the current invention is directed to determination and employment of artificial COT sequences. However, use of viral-DNA sequences in vaccine design is certainly well known and frequently practiced. There are an extremely large number of examples of using viral-DNA sequences to construct vaccines that raise antibodies in experimental animals and humans. The current application is directed to a bioinformatics approach to generating ancestral sequences via the COT algorithm, and then using the

ancestral sequences to design and prepare vaccines. Armed with the currently disclosed approach to vaccine design, and with the ancestral sequences in hand, those ordinarily skilled in the art can employ those sequences to design and produce vaccines.

In section 18 of the Office Action, the Examiner states: "The specification does not contain any working examples to show how to use the COT sequences, including SEQ ID NO:25. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention." Applicants' current representative has found a number of examples for use of COT sequences in the current application, beginning at least with paragraph [0188] on page 52 of the current application and extending to the end of the current application. Furthermore, Applicants' representative knows of no definition of the phrase "working example," and the Examiner has provided no definition. The Examiner implies that M.P.E.P. §2164.05(a) requires that an applicant provide working examples, but M.P.E.P. §2164.05(a) does not so require applicants to provide working examples. In fact, M.P.E.P. §2164.02 explicitly states that an application may satisfy the 35 U.S.C. §112, first paragraph requirement without providing a working example. In Applicants' representative's respectfully offered opinion, the Examiner has miscited the M.P.E.P. and falsely implied that working examples are required of applicants. Furthermore, the Examiner has appeared to have completely disregarded, in making the assertions in support of the 35 U.S.C. §112 rejections of claims 15, 19-22, 25-30, 45, 46, 48, and 63, the large number of examples provided in the current application. Applicants' representative also notes that the current application provides a very detailed description of how ancestral sequences may be generated using the COT computational technique. Having the COT sequences in hand for a particular virus, those skilled in the art of vaccine design and vaccine production would be capable of designing and producing vaccines that incorporate COT-determined ancestral sequences.

CONCLUSION

Applicants respectfully submit that all statutory requirements are met and that the present application is allowable over all the references of record. Therefore, Applicants respectfully request that the present application be passed to issue.

Respectfully submitted,
James I Mullins et al.
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By _____
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CLAIMS APPENDIX

1 – 14. (Cancelled)

15. (previously presented) An isolated expression construct comprising the following operably linked elements: a transcriptional promoter; a nucleic acid sequence that encodes the polypeptide encoded by SEQ ID NO:25; and a transcriptional terminator.

16 – 18. (Cancelled)

19. (Original) The expression construct of claim 15, wherein the transcriptional promoter is a heterologous promoter.

20. (Original) The expression construct of claim 19, wherein the promoter is a cytomegalovirus promoter.

21. (Original) A cultured prokaryotic or eukaryotic cell transformed or transfected with the expression construct of claim 15.

22. (Original) The eukaryotic cell of claim 21, which is a mammalian cell.

23 – 24. (Cancelled)

25. (Original) The prokaryotic cell of claim 21, which is an E. coli cell.

26. (Original) The eukaryotic cell of claim 21, which is an S. cerevisiae cell.

27. (Original) The eukaryotic cell of claim 21, which is a human cell.

28. (Original) A vector comprising the expression construct of claim 15.

29. (Original) The vector of claim 28, wherein the nucleic acid sequence is operably linked to a Semlike Forest Virus replicon, and wherein the resulting recombinant replicon is operably

linked to a cytomegalovirus promoter.

30. (Original) An isolated host cell comprising the vector of claim 28.

31 – 44. (Cancelled)

45. (previously presented) An isolated COT viral gene sequence, wherein the sequence is at least 70% identical to SEQ ID NO:25.

46. (previously presented) The COT viral gene sequence of claim 45, wherein the COT viral gene sequence is at least 90% identical to SEQ ID NO:25.

47.(Cancelled)

48. (previously presented) The COT viral gene sequence of claim 45, wherein the COT viral sequence is at least 95% identical to SEQ ID NO:25, and wherein the sequence does not have 100% identity with any circulating variant.

49 – 62. (Cancelled)

63. (previously presented) The COT viral gene sequence of claim 45, wherein the COT viral sequence comprises SEQ ID

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.